

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS DATA**I. General Information**

K 961067

A. Submitted By: MedTrak International, Inc.
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- B. Device Trade Name: *BURN-AID* Hydrogel
BURN-AID Hydrogel Burn Dressing
BURN-AID Hydrogel Burn Blanket
Common Name: Burn Dressing, Blanket, & Gel
Classification Name: Burn Dressing, Blanket, & Gel
- C. Predicate Device: BurnFree Hydrogel, Dressing & Blanket
Burnshield Hydrogel, Dressing & Blanket
- D. Device Description:

BURN-AID Hydrogel is a water-based gel containing extract of Melaleuca alternifolia (tea tree oil) and various stabilizers, emulsifiers and preservatives. The tea tree oil acts as an antiseptic. This gel is available in single-use packets for direct application to the skin. The *BURN-AID* Burn Dressing is composed of a soft foam sheet impregnated with the *BURN-AID* Hydrogel. The *BURN-AID* Burn Blanket is composed of pure virgin wool saturated with the *BURN-AID* Hydrogel.

E. Indications for Use:

The *BURN-AID* Hydrogel, Burn Dressing and Burn Blanket are indicated for single use as a pre-medical first aid for first- and second-degree burns and scalds to cool, soothe and moisturize the burn area.

F. Device Comparison:

The *BURN-AID* products are substantially equivalent to various other currently legally marketed burn products, including those marketed under the name BurnFree and Burnshield. Each of these products are available as a

hydrogel containing tea tree oil, as a burn dressing impregnated with the hydrogel, or as a burn blanket impregnated with the hydrogel.

II. Testing: No additional testing necessary